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*February 7, 1989*



Captain A.J. Melaragno
United States Navy
Director of Research & Development
Naval Medical Research & Development Command
Naval Medical Command, National Capital Region
Bethesda, MD 20814-5044

Dear Dr. Melaragno:

I apologize for the poor quality of the final report on our ONR contract number N00014-84-C-0725. Enclosed is a new hard copy which should be suitable for your purposes.

Sincerely,

Clifford M. Herman, M.D.
Professor of Surgery
Director, Surgery Residency Program
CMH:bj
Encl.

Final Report on ONR Contract N00014-84-C-0725
Trauma Patient Followup Registry
31 July 1987

## Overview

The goal of this project has been to explore and document the information management capabilities needed to develope a transportable spartan but automated patient care record for trauma patients which would be a model for a comparable system to be used in the echelons of care employed by military operational medicine and for which the Fleet Marine Force is the model. While this goal has remained invariant, the objectives needed to achieve this goal have changed, as has the original strategy, because of the opportunities presented by recent events. The major objectives at the completion of this contract, 31 July 1987, are:

- Develope a generic automated patient record structure compatible with CHCS, VA DHCP, USPHS systems and standards for non-federal automated systems.
- Utilize standardized terminologies and data representations.
- Identify strategies for quickly and easily educating trauma care personnel in the use of automated information systems in the care process.
- Develope a Trauma Registry linked to the care record structure for use as a research database.

The first major objective, that of modelling the transportable patient care record on the Veterans Administration DHCP system, remains firm but, because of the progress of the internal VA Special Interest User's Groups (SIUGs) has not been as rapid as expected, definition of the segments of the trauma care record that are consistent with DHCP has been held back. Moreover, the one alternative configuration in the CHCS competition that is based upon DHCP has had to introduce new record structuring concepts for care record segments that may differ from the current approach of DHCP. These changes have held back a consensus on the basic logical structure of the record. An ASTM sponsored national voluntary consensus activity on the structure and content of the primary care record, supported by the American Medical Record Association (AMRA),

has been organized. One product of this effort, supported by our work, has been the production of a Standard Description of the Registration - Admitting, Discharge and Transfer Process as a first step. This standard describes the Demographic segment of the care record. The next step, a standard description of the entire primary care record structure and content is well along but will require inputs from the federal VA DHCP, USPHS and DoD CHCS public projects as powerful models to organize the consensus from the private sector. While involvement of federal agencies in the ASTM activities has accelerated, this process has a ways to go before it is complete. In spite of this, our current prototype data dictionary has already incorporated the available features of DHCP and CHCS as well as those coming from the private sector.

Another major objective has been to utilize terminologies that are widely supported by consenses, particularly those for describing injury. The commencement of the 10th Revision of the International Classification of Diseases by the World Health Organization coincided with the establishment of an ASTM voluntary consensus activity to define generic well-structured biomedical nomenclatures. These two complementary activities provided the opportunity to define these lexicons to be mutually consistent so that they will meet the need for a common terminology of injury. While these efforts are still ongoing, we have had a major role in both of them and have incorporated the emerging terminologies into our prototype architecture. These ASTM Standards efforts are now also providing input into the CDC national injury program. As a result, our efforts regarding terminologies have already contributed to the award from CDC of a Center Grant for Injury Prevention to this institution.

A third major objective has been to identify the approaches to educating the potential users about the capabilities of the system and the procedures for using it. We have used the iterative design process to compose dialogs for the Trauma Registry component of the system and to explore the layout and style of interaction most appropriate in a trauma care environment. The problem of getting patient care data into the system is not a trivial task and, while numerous approaches may be used, there is little consensus about the ways to gather descriptive data about the care rendered in a trauma setting. When the record structuring and data representation (terminology) issues are more completely resolved, it will become clearer how to approach the data capture process. Nevertheless, the data entry screens and dialogs for both the Registry and the Trauma Care Record initial segments have been developed to be as convenient as possible for learning about the system.

The fourth major objective was to structure and define a Trauma Registry research database that would be strongly compatible with the automated Trauma Care Record so that so that data could be





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easily and accurately abstracted from the care record and posted into the Registry. The structure of this registry is open-ended and can receive new data from the care record, as the need for it is identified. The emphasis in the Registry has been directed at ensuring accuracy and completeness of the collected data rather than merely increasing the number of elements for which data is collected; the number of elements can be extended when the ability to machine-abstract the care record becomes available with the regular use of the automated care record.

## Specific Achievements

### Record Structure

In order to have a transportable record structure that can be received by DoD fixed definitive care facilties, a common generalized care record structure must be agreed upon. The VA DHCP "Patient File" record structure is based on, and is consistent with, work AMRA began in the mid 70s when DHCP began. DHCP presently consists primarily of Registration-Admitting, Discharge and Transfer(R-ADT) information, although a number of VA facilities have added local extensions to contain clinical data. The PHS/Indian Health Service (IHS) has adapted the VA DHCP model and added a considerable number of data elements relating to ambulatory care encounters. The DHCP alternative for CHCS has adopted a number of conventions from these efforts but no universal consensus has yet been agreed upon. That general consensus will be arrived at through the ASTM process which will involve all of the clinical specialty societies as well as federal agencies.

Because it was recognized that this route was the only one likely to be effective in establishing common record structuring conventions that were likely to be both adhered to by all providers and capable of producing the conceptual framework for a transportability format that would draw on the existing federal models, one of our investigators (AWF) helped establish the E31.12 Subcommittee on Medical Informatics responsible for this area and is

the current Secretary . The care-record transportability convention itself will be the product of E-31.11 Subcommitte on Data Exchange, which we also helped form, but which will draw on the work of E-31.12. The Subcommittee on Data Exchange has recently produced a Standard Specification for the Exchange of Laboratory Requests and Results Between Computing Systems in which we were heavily involved. Work in this subcommittee has just begun on two new projects: a specification for the exchange of medication data and a draft of the approach to specifying the way to exchange the patient care record, which this facility is initiating.

It is important to recognize that the two activities of record structure definition and record transportability conventions are inextricably linked. By contributing the experience of this project to the standards deliberations we have been able to reflect the current consensus in our protoype care record structure. The details of this structure is contained in the current version of TPFUIS Design Manual (Attachment I). The way that we have related the information in this project to the anticipated needs of the FMF Field Information System was to create a parallel prototype system for the FMF in which the record structure data elements identified in the FMF Casualty Care workshops (1,2) and the CHCS specification were placed to avoid conflict with VA DHCP elements but in a way that was consistent with the emerging consensus model logical structure being used in the ASTM process. The current draft is enclosed as Attachment IV. This process will ensure commonality between civilian automated systems and military field medical records through the medium of the transportability convention, when completed.

As a means of analyzing the existing paper record, validating the emerging logical data model against this analysis and coordinating the identified elements with the emerging consensus we created a database (3) to reflect the main dimensions by which data elements are viewed and to record data about the data element attributes which can then be manipulated in parallel with the emerging consensus logical record structure. This database allowed us to be able to identify the way our current local paper record system reflects or conflicts with the emerging consensus. A similar paper analysis of the military paper record system(4) has not yet been incorporated into the data base, but could be when a common DoD ground is identified for relating that analysis to the CHCS specification. Just one of the many possible perspectives of the current data element database is presented in Attachment VI while the reference logical model is shown in Attachment VII. The Data Dictionary for this database is shown in Attachment V.

This database approach is far superior to the PSA/PSL representation used to specify the CHCS because it has the ability to define the logical structure of the record. It also posseeses

the ability to be linked to system specification databases that define requirements and functions which, it should be noted, should be able to specify the logical structure of the databases as part of the system specification. Though the potential for software tools to aid in the full system definition process is quite a ways from being met, the present approach has been a major aid in our input into the ASTM patient care record structuring effort. The three year contract period has simply been insufficient to follow the consensus procedure to its conclusion, but it has allowed this project to establish the framework and the intial conventions for defining the information needs of trauma care with regard to the global framework that will be needed for the transportable record.

Attention should also be called to the efforts now underway to define the patient record information required for occupational health surveillance. The ASTM E-34 Committee on Occupational Health is collaborating with E31.12's efforts in this direction. Nevertheless, the various national agencies having an interest in the health effects of hazardous substances have not yet been brought together in a concerted way. This effort is important for a medical record for military operational medicine information systems because most of the needed data for occupational health are recorded as part of the routine "sick call" encounters. This same data also provides the information needed for other clinical perspectives, such as the followup of injuries. Such data must be dealt with consistently and within the general structure of the care record but patient data must be presented uniquely to each practitioner having a specialist perspective.

Likewise, The combat casualty care aspects of the record should draw on the convergence of the efforts of ASTM's F-30 Emergency Medical Services Committee, the CDC national Injury Control Program (which also includes the CPSC and DOT/NHTSA) in defining: pre-hospital information requirements, emergency medical treatment data and emergency medical services planning and managerial databases. The collaborative aspects of this joint effort has just begun.

Our current prototype reflects a number of the capabilties that will eventually be addessed by these two perspectives but our strategy has been to implement only those data elements and segments of the record that reflect a clear emerging consensus. Nevertheless, the DHCP structure is robust enough to accommodate all of the logical structures which are likely to be proposed.

## Terminologies

The issue of terminologies for a transportable care record system revolves around the identification of the mode of representing data for each data element in the logical data structure. Some data elements may require a sublexicon of terms that have meaning only within the context of that element's location in the record. Other data elements may have more general use and thus appear in several places in the record, including appearing as free text. Some current automated care record systems utilize a master dictionary of terms which identifies the context of the term and directs where it is to be stored within the record. It is not clear that this approach will work in a trauma care setting where much of the data is numeric, date-time valued or from limited lexicons. Narrative text presents a major data capture problem which it is known would be very difficult to solve either in combat casualty care or in civiliain mass casualty situations. Nevertheless, we have focussed on a limited number of sublexicons, the two most important of which are: nature-of-injury and mode-of-injury. Because the 10th Revision of the International Classification of Diseases (ICD) and the ASTM E31.12 Medical Informatics activities on Biomedical Nomenclature commenced concurrently, we elected to participate in both of these efforts in order to be able to affect the development of a common consensus on a terminology of injury.

With regard to nature-of-injury, the proposed 10th Revision of ICD is organized first by anatomic location and then by type of injury, though not as specifically stated as the Abbreviated Injury Scale (AIS-85) terminology. Moreover, because the wording of the ICD-10 sections for nature-of-injury is less specific than that of AIS-85, it leads to several ambiguities affecting injury scaling. It is, however, much improved over the ICD-9-CM terminology. Furthermore, John Hopkins University (JHU), in collaboration with the American Association for Automotive Medicine (AAAM) proprietors of AIS-85, produced a mapping of the AIS-85 scale values into the ICD-9-CM lexicon, which we obtained, courtesy of Dr. Ellen MacKenzie, Johns Hopkins. We are currently collaborating with AAAM and JHU as part of the ASTM process in order to produce a unified dictionary of terms each having a code for ICD-9-CM, AIS-85, ICD-10 and SNOMED. This unification will enable crosswalks among the existing terminologies to be related to a single preferred term which will be expressed using the generic rules of terminology to be produced by ASTM E31.12. The dictionary will also contain other attributes associated with these terms and it will thus become the central common terminology for describing nature of injury.

One of our contributions has been to formulate a structured way to state the three major attributes of the nature-of-injury term: general body location, detailed location and type of injury in a

formal way so that terms can be explicitly understood and indexed in a conceptually natural way useful to practitioners. The object of this way to express the term was to make it easy and accurate to capture injury data for the care record once at the source. Though much remains to be done in developing the consensus, we have incorporated this representation into the lexicons for our prototype and into our experimentation regarding the best way to access, display and use these data. These experimental efforts are also being used to foster the consensus process. One benefit of this approach is that, given an accurate and complete list of terms of injury, an injury severity score (ISS) and the AIS profile for each body region is immediately available. That benefit has already been useful in the Trauma Registry Component of our prototype but the demonstration of the benefits of the immediate availablity of ISS and AIS data to the Emergency Room practitioner still needs to be defined.

With regard to the mode-of-injury, we undertook to propose a completely new structuring of the terms based upon the five attributes: mechanism, agent, activity, intent and setting that were reflected in the "E" codes of ICD-9-CM. By wide agreement the ICD-9-CM organization was very confusing because it was first grouped by intent, the most unreliable attribute, rather than by mechanism, the highest priority, most reliable and intuitively obvious attribute. In concert with the CDC Injury Control Program we have proposed to WHO that ICD-10 use the first proposal for mode-of-injury made jointly by CDC and the Nordic Medical Statistics Council (NOMESCO) which stated that the lexicon be ordered first by by mechanism and then by the other attributes in the priority noted above. If that proposal is eventually accepted, this representation will markedly simplify the recording of mode-of-injury in the trauma care record. This ability to easily and quickly record mode-of-injury will significantly increase the availablity of accurate and detailed mode of injury data for epidemiologic purposes. The use of this convention has immediate relevance for the capture of mode-of-injury data from combat casualties. The availablity of mode and nature of injury data in the combat setting will provide explicit derived data which can be used in the patient distribution activities of Medical Regulating, such as that addressed by the Army TAMMIS system. In fact, one of the major reasons for our effort was to be able to easily and reliably get that information in a combat setting. DoD will need to convoke a military consensus group to agree on the extensions needed to characterize combat injuries, but this can not be done until the outcome of the WHO deliberations are known.

With respect to other terminologies, we considered the terms used for number of other data elements, such as type of admission, disposition and procedures. Procedure terminology is the most important; both operative procedures and laboratory terms need a

common lexicons. We have participated in the ASTM Task Group which is developing a convention for Laboratory Test and Analyte names that will provide a common terminology for both ordering laboratory tests and reporting the results. Because few, if any, current laboratory information systems report test data by posting directly to the patient care record, the main reporting route is by printed summaries. When machine posting becomes available, a common terminology will be required; a transportable record is vitally dependent upon this commonality of terms.

With regard to operative procedures, ICD-9 terms are widely used for inpatients but CPT-4 terms are used for outpatients and these two terminologies are phrased differently; SNOMED Procedure terms are used in surgical pathology reports. We have identified a hierarchy of attributes for procedure terminology starting with body location and type of procedure as the most important, but we have not yet developed a specific proposal to ASTM at this time because WHO will not include Procedure terms in the 10th Revision. Therefore the urgency to restructure the operative procedure terms does not yet have the priority of obtaining an agreement on the nature-of-injury and mode-of-injury terminology. Procedure terms will be dealt with as soon as these other terminologies are well on their way to consensus.

## Instruction in Use

One approach to learning about use of the trauma care record system involves the design of attractive interactive dialogs. The data that is generally captured in clinical settings is more complex than is regularly realized. The mental tasks that take place are more complicated than most have recogized. For example, in order to record the structured terms for diagnoses or operative procedures explicitly and in a detailed fashion, the presentation of the information needed to find a specific term in even limited lexicons needs to offer a quick and easy means of looking up these terms. One major aid is a well designed lexicon, described above, but these terms must be rapidly and easily accessible in a powerful way. Windowing abilities abound in standalone micro-computers and workstations needed to record clinical observations at thee bedside. Using recent software toolkits utilities for the ANSI X11.1 MUMPS environment and improved terminology, we have experimented with menu/window presentation techniques that focus attention on regions of the lexicon containing the terms relating to the selections.

In addition to more interactive visual displays we have also initiated the linking of interactive segments of user dialog to help prompts within the softare tools. In concert with VA investigators, we have been using a version of the authoring language PILOT/MUMPS that is callable from within the system building tools (VA FileMan). PILOT is an authoring language for managing dialog in instructional settings; the MUMPS implementation of it has an important property that gives it access to the underlying MUMPS environment where it can call upon embedded instructional examples of how to use the system. Experiments in learning how to use this capability in a trauma setting are embryonic since the system is still being defined to meet the emerging standards. These capabilties were implemented to identify the feasibility of conducting online instruction when the system approaches its initial testing period with untrained users.

## Linked Trauma Registry

The Trauma Registry component was an out growth of our structuring of the Garrick-Carey Battle Casualty Database, ONR Contract N00014-83-0568 Mod 2 and became the vehicle for looking at the data elements to be incorporated into the Trauma Care Record. This Registry Component categorized and focused on the data that would characterize the trauma patient population and highlight the data issues that must be dealt with in the patient care record. The technical capabilties of the Trauma Registry are described in refs 4 & 5 and the Documentation Manuals are found in Attachment II & III. The major achievements are first, that the registry record structure is organized to be closely similar to the prototype patient record. For many of the data elements identical lexicons are used for the corresponding data elements. Because of the use of the VA FileManager and the pointing technique, the entries in the lexicon files can be categorized for the trauma registry and can be seen as category names from the registry but as the detailed entry from the care record. For many of the corresponding data elements in the two databases, the data elements access the same lexicon. This feature facilititates automatic abstracting of cases from the care record to the registry.

Even though at the time of completion of this contract, the care record prototype is not being used to capture patient data into the automated record, the initial ability to conduct automatic abstracting of that record is in place. Obviously, this abstracting

facility needs to be extensively tested before it can be considered operational but the present environment has demonstrated its benefits which are due to decreased personnel time and to increased accuracy and convenience in collecting this data via the direct abstract from the patient care record. Such an ability will be necessary if the incentives for trauma facilities to generally maintain an active trauma registry are expected to be in place before the regular use of a registry is mandated as part of hospital routine operations.

From the work done on the Battle Casualty Database, this trauma registry model was intended to help define how this same data would be employed in analyzing casualty care in the field, beyond the current capabilties which are projected for TAMMIS and other data systems supporting patient distribution activities of Medical Regulating. The capabilities of the Trauma Registry are in addition to the Patient Accounting functions of these systems because the registry captures a variety of clinical data, both treatment and outcome measures, which were not originally intended capabilities of a system like TAMMIS. The registry also complements the automated care record by condensing and categorizing much of the data originating in the care record and decoupling access to this data from the ongoing activities involved in patient care, a distinction that has been noted in the literature(7).

The Trauma Patient Care Followup Information System (TPFUIS) prototype technical details are contained in the TPFUIS Design Manual, Attachment I. It is important here to note the basic capabilities of that prototype, and any parallels with the FMF Prototype (see FMF Prototype Design Manual, Attachment V). One important feature of the TPFUIS prototype is its compatibility with VA DHCP and the DHCP-alternative CHCS System. Insofar as we have been able to gather information about the CHCS alternative, the Registration ADT functions of that alternative, the FMF Prototype and TPFUIS are consistent not only with each other but also with the ASTM requirements (8) for standard functions. The FMF and TPFUIS prototypes extend the data in the R-ADT segments of the DHCP and CHCS-alternative record to include pre-hospital and emergency room data about injured patients. The placement of these elements is based upon our experience with the Trauma Registry and it does not currently collide with VA DHCP. Nevertheless, this placement of data elements is provisional because the work of ASTM E-31 has not yet identified, via its coordination with ASTM F-30, Emergency Medical Services, the consolidated requirements for both the pre-hospital and in-hospital acute care that may be jointly identified by the participating specialty societies. The structure of this prototype, however, will allow these additions/changes to be made as soon as consensus is reached. The record segments containing problem list, clinical orders, laboratory/diagnostic data, medications, medical history, physical exams and inpatient care have all been identified

in the ASTM logical model but our implementation of them has awaited clearer understanding of any joint agreements between VA DHCP, PHS/IHS and CHCS regarding a common placement of these segments before proceeding. The placement of operative data within the inpatient segment likewise requires further definition. At the latest, the VA Surgical SIUG, which advises DHCP on this subsegment, had not produced a recommendation.

## Implementation Infrastructure

The project software environment has utilized the ANS X11.1 MUMPS language and software management environment. Because the project is modelled on the DHCP, it currently uses V. 17.08C of VA FileMan and V. 5.0 of KERNEL. Through use of these sysstem-building tools, the ability to link the Trauma Registry component and the TPFUIS component in a consistent fashion is provided. We have also used a proprietary software toolkit from Patterson-Gray Associates that handles menus and other display aids. There are a number of vendors products of this type on the markeet that facilitiate screen displays. The techniques used here are, therfore, not unique but have slightly different properties than if other tools had been used. The environment used is a common multi-user ANS X11.1 MUMPS implementation, InterSystems M11+, and we have avoided implementation-dependent features, except where clearly sequestered. The systems can therefore be ported to any environment offering a valid ANS X11.1 MUMPS language processor; the newer features of the language, such as parameter passing, are not used. The Trauma Registry component using the tool kit utility generally is, however, not strictly device independent because it uses function-key escape sequences. Nevertheless, the software understands the device characteristsics via tables which currently contain attributes for only the most common devices. Therefore, if further device attributes are included in the tables, a wide variety of devices can potentialy be used with the Registry. These screen display techniques are not yet fully used in the TPFUIS component where we still use standard VA FileMan scrolling dialog techniques in many places during the requirements definition phase.

The above achievements are noted to underline the fact that though the patient care record component is still in a rough prototype phase in order to allow experimentation with the implications of standards for the patient care record, the Trauma Registry component is a fully operational working tool. Even though daily data are being collected using this component and research into aspects of

patient care is being conducted, the Registry, too, is still in a state of software evolution. Over the past four years the registry has migrated from the original Apple II+ ANSI X11.1 MUMPS environment to the current PDP 11/73 host and it has undergone a number of restructurings to accommodate new requirements for the representation of data elements or for the reorganization of database data elements, based on active use. No data was lost in any of these actions nor was the schedule of data collection delayed unduely. This was due entirely to the power of the ANS X11.1 environment. Further exploration and documentation of the information processing conventions needed to structure a transportable patient care record will be dependent upon this technical capabiltity.

It is important at this point in the discussion of the implementation setting to address the approach to engineering and documenting the software for this project. The goal of the project was to "explore and document" concepts of information representation and structuring, an activity that is classed as requirements definition. It is a requirement to not only document the tools used but also to, if possible, design modules that are capable of evolving into fully operational systems. Therefore, good system documentation is required. Because one of the originally envisioned tasks was, and still is, to fully excercise the patient care record system in an active trauma care facilitty, the approach to jointly documenting both the concepts and the tools needs to recognize any standards that describe good software engineering practice. In recent years, several national voluntary consensus standards groups have published such standards (9). It is important to note that while each of these published standards represents a major step in documenting the activities involved in engineering a "product", they have each not fully recognized the approaches that are termed "Rapid Prototyping" and "Artificial Intelligence". These terms are still indistinct in what they mean to differrent groups.

The achievements of this report were conducted using the "Rapid Prototyping" and "Iterative Developement" (10) approaches. As noted earlier(11), the requirements definition activities - the earliest phase - can be markedly accelerated by using the rapid prototype approach. What is done in that approach appears outwardly to be markedly different from the process described in a number of software engineering standards but it really is not. Basically, however, each iteration undergoes active change leading to improvement of a given feature through online coding dialog, test, debugging and retest, all procedures in the traditional approach. A development period which leads to a stable system is termed a new "Version", which can then be archived and controlled by configuration management procedures and the changes documented both as software and requirement (conceptual) changes. While we, in a research environment do not maintain a strict system of

configuration management or validation/verification/correctness activities because these are based largely upon pre-determined requirements, we do test and document the system at various nodal points. Attachments I & III are examples of the documentation of the two components at specific nodes but should not be looked at as final or definitive because of the evolutionary nature of the project. This documentation is an important aid in being able to inter-relate the two components to each other and to VA DHCP and CHCS both at the conceptual level and the physical level used to port systems from one environment to another. It should be clearly understood that such documentation is only a "snapshot" of the the system as of 31 July 1987. Nevertheless, the procedures utilized in this project can be related to those recommended in these various software engineering standards for various points in the lifecycle, even though such standards do not yet explicitly deal with "Rapid Protyping" and "Iterative Developement" processes in life cycles. Such documentation will be required for eventually engineering operational field medical information systems.

Our experiments in developing responsible, yet practical, approaches to the documentation of a system used for requirements definition has further benefitted the ANSI X11.1 MUMPS standards process in formulating documentation standards for the MUMPS environment that are consistent with emerging software engineering standards and practice, since one of the investigators has chaired the SC #3 on Documentation for the ANSI X11.1 body since 1978. He has thus been able to use the lessons of this project to help establish coordination of ANSI X11.1 with ISO, ANSI X3, ASTM and IEEE with regard to documentation and project management standards. This coordination has been possible because in the last few years all of these standards efforts have identified the need to coordinate their activities to produce complementary standards that are accepted and used to yield quality software. The influence, of course, has been mutual.

## Impacts of the System

The system has had a number of impacts on the trauma care environment at Harborview and also upon other associated organizations and projects. The details of the technical impacts on standards groups were dealt with in the sections above. The details of the impacts on trauma care will be dealt with in this section.

The impacts of better information availability on the clinical,

research and management aspects of trauma care are not always easy to quantify. To deal first with the clinical aspects, i.e. providing information to those that care for patients, the availability of synoptic information has provided a heightened awareness of what kinds of patients the facility is actually receiving while specific care data has focussed on particular patient problem areas. For example, the availability of the Annual Summary to the various Nursing Supervisors in the trauma units has led to their using it for a variety of planning and management purposes. Moreover, data on specific patient's profiles have been used by these same supervisors for case reviews. In view of the time lag due to capturing the data from paper documents, this benefit has been less than might be, if machine-aided abstracting were available.

The research aspects involve clinical management issues, such as blood usage, which has been a major interest of at least one member of the Sugery faculty. The ability to get, store and extract data about blood usage has enabled numerous discussions about policies for blood resource management as well as the production of research studies for the literature. A variety of research projects, such as that on head injury, have used data and data gathering procedures developed by the Trauma Registry in order to design rigorous valid detailed clinical research studies. The CDC-funded Injury Prevention Cnter has made extensive use of the Registry data in designing interventions for pediatric injury and for organizing arguments made to the state legislature in support of legislation to require helmets for motorcycle riders in this state. The extent of the studies supported range, forr example, from a focussed look at knee injuries for the Radiology Dept to a broad look at bicycle head injury. The value of the Registry to all of the institution's users is based upon the value to them of a database of complete, accurate data for the data that is collected. That value would be increased if all of the data collected were available within 24-72 hours. This can be achieved with the current constellation of data elements when the data are collected for the patient care record so that abstracting can be machine-aided, whereas this task becomes very difficult when the source is the manual paper record. When the constellation of data elements is expanded to include complex selection criteria for clinical events to be abstracted, machine-aided abstracting will provide the only economically feasible alternative for attaining full synoptic and selected care data quickly. Thus, decisions relating to clinical management policy that depend upon timely data will be major beneficiaries of the automated collection of trauma patient care data.

The health care facility management isssues that have benefitted from the availablitiy of Trauma Registry data include focussed studies of costs on selected classes of patients which draw on the clinical data obtained by the Trauma Registry that are not available

in the current management data. Our efforts to input case mix data on Registry patients that is extracted from the State management database will continue. Several studies are underway to compare the cost and resource consumption profiles that are derived from the case data collected by the Trauma registry with that obtained from the case mix database. The results from these studies will reveal whether there are inaccuracies in the estimated resource consumption for trauma patients and may suggets changes in the reimbursment policies. It is important here to recognize the overlap between data characterized as "clinical" and data usually thought of as "management" in order to perceive the ways that these two perspectives may be synergistic in developing the policies used in operating a trauma care facility.

The list of recorded studies requesting data from the Trauma registry and the bibliography of reports and publications emanating from this project are contained in Table I and Appendix I respctively.

## FUTURE CHALLENGES

This project is not complete. The goals remain. Because of the new realities of important new standards activities that could produce wide consensus on the establishment of the concepts that underpin transportability, the objectives concerning the structuring of a transportable, generalized trauma patient care record had to be modified. It was more important to establish the organizational and procedural infrastructure that could achieve those objectives than to rapidly push into a working prototype that was not based upon central concepts. Now that standards infrastructure is in place. The challenge for the future is to push the standards machinery to reach fundamental consenses on core issues as rapidly as is possible. The core concepts of a common care record logical structure definition, a transport format convention and commonly accepted and used terminologies will be the main thrusts in that effort. The approach that this project should take, based upon the achievements to date, will now be discussed.

**Complete Implementation of a Record Compatible with DHCP and CHS:**

The major public models for the logical structure of the primary care record are the VA DHCP and the DoD CHCS; the PHS Indian Health Service is already using the DHCP model and other activities within PHS are also adopting, or considering adopting, the DHCP model. The DoD CHCS's DHCP-alternative is being closely evaluated with three others in the competition for automation of fixed definitive care facilties; at the very minimum, however, that alternative will operate in a military MTF for three years and will thus be an important public model for the concepts essential to automted primary care record systems. As such a model, it will undoubtedly have major influence on the VA's DHCP in any case. DHCP and its CHCS-alternative have been our models for a powerful, robust field medical system concept capable of accommodating trauma care. The future challenge will be to flesh out those data areas that have been dealt with neither by VA DHCP nor by CHCS. Additional data areas serving Occupational Health are relevent to a comprehensive automated field medical care record and they are complementary to trauma care because they also encompass the disease, non-battle injury (DNBI) information requirements of a field system in addition to accommodating the routine care of non-wartime field operations of deployed forces. These areas are covered by other standards groups operating in concert with the ASTM E-31 information system activities. The challenge at this contract termination is to develope a consistent conceptual framework that enables all of these health care issues to be evenly addressed.

**Develope and Test a Transport Format Consistent with National Standards:**

When the RATIONALE for the logical structure of the primary care record becomes clear, a notation for describing that structure on a transfer medium can be devised. Such an effort has just begun, based upon some of the perspectives of this project. The need for a common transfer format has been identified some years ago by the American Medical Record Association. The transfer convention's utility to a care facility is based upon the value of receiving a clear, systematic record of prior care, in an automated form, from the transferring facility when the patient arrives at a receiving facility. This is an identified generic requirement for all health care. Its value to trauma care and military echeloned care lies in the ability of a casualty care MTF to get data regarding prior care in a timely fashion for severely injured patients. Until very

recently this requirement has had a remote chance of being met. The consensus on a record structuring convent\tion will make possible the use of a formatting convention that will reflect a universal logical structure that all facilities can either produce or read so that data on the transfer medium can be inserted into their automated care record system. Since few automated patient care record systems have existed until recently and those that did exist did not accommodate longitudinal patient care data, the DHCP model has provided the large public model that illustrates the potential of the transportable care record, in spite of the fact that the VA patients generally are not as highly mobile as injured patients or that the VA has not yet extensively tested the record transfer capability at this time. The influence on the health care industry of the ermrging consensus regarding the primary care record logical structure, of the VA DHCP and of the CHCS competition will make it possible to test this capabiltiy on highly mobile patients. The VA will want to do this to be able to discharge its responsibility to DoD under the CMCHS agreements in additon to improving its ability to manage the care of its mandated constituents. Therefore, the challenge posed at the time of this contract completion is heightened beyond just the patient care transportability requirements of trauma care to include its potential benefit to civilian health care generally.

The critical capabilties needed to produce software features for transportability are already built into the CHCS DHCP-alternative software being delivered as part of the current competition. The challenge to this project is to obtain permission to use these features and to provide a test bed for the concepts used in the transport format convention being produced within ASTM standards activity. If that is done, the transportability concepts can be demonstrated and the validity of the convention shown. This will allow these common conventions to be introduced into the field medical information software at the earliest time, thereby making possible force medical readiness conditions not heretofore attainable. Though the benefits to civilian care are equally great, but not so urgent, the two requiremenbts are synergistic and will have major effects on the organization of patient care when such data can regularly be transferred from facility to facility. The full benefits to patient care of the telecomunications medium can then be realized. So that is the true challenge and the information transportability critical step which the other standards efforts underpin.

**Link the Care Record with the DIN/PACS Structure:**

Another major component in the exchange of patient data is the exchange of image type data formats. In recent years, the the use of imaging technology to gain non-invasive data on patients has used digital forms of image management instead of traditional film technology. The quality of digital data is now such that digital images can convey as much information as can be contained in film images but digital methods have far more power to extract really meaningful clinical information than does the film medium. While both the digital imaging technology and the science of identifying biological signals produced by patients that can be manipulated with this technology are in the growth phase, the present state of techology forces the patient record issues to be addressed at this time and related to the portable care record issues. Images can now be transmitted, stored and archived by a wide variety of telecommunications technology. In fact during the 1970's the U. S. Navy demonstrated the communication and interpretation of images from deployed ships half around the world and it commissioned prototype shipboard communications stations to be designed and built to tranfer both images and patient record data in a variety of ways from ship-to-ship and ship-to-shore in a fashion compatible with other demonstrations of the use of this same technology in medically underserved areas. The challenge identified at the completion of this contract is to develope those conventions for linking the record and the images together as an integral structure which can be transferred together. This capability is particularly relevent to trauma care where the clinical record must be available for optimal interpretation of recorded images. The applicability of this requirement to casualty care is obvious.

The DIN/PACS project at this institution has only recently commenced but its significance with respect to this project was never underestimated and was expostulated during the formulation of the DIN/PACS proposals from this institution. The challenge will be to coordinate the thrusts of the two projects in order to produce and test the conventions that will allow consistent integration of image and primary care record data. The tranportablity of the combined data package must then be adequately demonstrated in an active trauma care setting.

**Extend and Test Automatic Abstracting:**

It has been self-evident(12) for some time that most of the epidemiologic and management data about health care and health care

services comes largely from the primary care record, augmented by other records that contain data about resources not connected to an individual patient. It is, therefore, clear that the cost of extracting this information is far less from a systematic, automated primary care record than from a hand written manual paper record. With the arrival of a common convention for understanding the systematics of primary care record structure, the ability to abstract and categorize data into aggregates needed for management (such as cost identification and cost management) and for research (such as epidemiology and clinical research) is also enabled.

The challenge here is to understand how to focus this ability and give management personnel the data they need to manage resources and to give clinicians the case data needed to understand the processes of patient care. It was noted above that tools and techniques have been put in place for this activity. The DHCP environment has great potential for their use, but understanding the needs for management data and identify their origins in the primary care record will largely depend upon experience in using these tools, since the the management and patient care professionals have had little experience in direct dialog on this subject in the past. We have, in the past, advocated the use of such a dialog and now put software tools in place, such as the Trauma Registry and the prototype primary care record, but the challenge will be to fully exercise this environment in order to identify the steps that are the most productive as well as the data that are the most enlightening. That is a major challenge.

## Interface with Standards for Pre-Hospital Care

Only in the last few years have patient care information professionals and the Emergency Medical Care Specialists and Traumatologists begun to discuss the information requirements of the entire Emergency Medical Services Support System. It is obvious that the pre-hospital care system should smoothly interface with the in-hospital trauma care system and yet the information management subsystems activities in both these environments have pursued largely independendent courses. In the military, the system is far more integrated when in wartime. However, the military has been forced to use the local civilian EMS for routine peacetime emergency care of its members because the civilian sector has largely not structured itself to use concepts learned from the military operation of the Continuum of Care. The challenge to the developement of information management of pre-hospital care data in

this project will be to work with the task groups from the different ASTM Committees dealing with the different phases of the problem and to implement and test as many of the proposed data management conventions as is feasible in order to help prove their value to information integration. We have helped establish those linkages but the real test for us, as for others, will be to provide sufficiently powerful prototype software tools for testing the proposed common conventions so that their benefits to both the pre-hospital and in-hospital practitioners will be self-evident and they will use them. With the current pace of standards development as rapid as it is, that testing time lies in the very near future.

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9. (a) IEEE Software Engineering Standards:

- ANSI/IEEE 729-1983 IEEE Standard Glossary of Software Engineering Terminoloy
- ANSI/IEEE 830-1984 IEEE Guide to Software Requirements Specification
- ANSI/IEEE 730-1984 IEEE Standard for Quality Assurance Plans
- IEEE P1074 D1.0 IEEE Standard for Life Cycle Processes

(b) ASTM Standards:

- ASTM E1113-86 Standard Guide for Project Definition of Computerized Sytems
- ANSI/ASTM E627-1982 Standard Guidelines for Documenting Computerized Laboratory Systems
- ASTM E622-81 Standard Guide for Computerized Systems
- ASTM E623-82 Standard Guideleines for Developing Function Requirements for Computerized Laboratory Systems
- ASTM E 730-80 Standard Guide for Developing Function Designs for Computerized Systems

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**Attachments**

I. TPFUIS Design Manual
II. Trauma Registry Design Manual
III. Trauma Registry User Manual
IV. FMF Prototype Design Manual
V. Data Element Catalog
VI. Data Element Inventory - one perspective
VII. Current (31 July 1987) Reference Logical Structure of the Primary Care Record